REMARKS

The Office Action

Claims 56 and 74-81 were pending in this application. Claims 1-55 and 57-73 were previously canceled. With this reply claims 78 and 79 are canceled and new claims 82-87 are added. Claims 56 and 74-81 stand rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. Claims 56 and 74-81 stand rejected under 35 U.S.C. § 103 for obviousness.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 56 and 74-81 stand rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. The Examiner asserts (i) the distinction between the general solid phase peptide synthesis ('SPPS') and the claimed invention is unclear where claims cover the pre-sequence peptide conjugated to the target peptide as the final product of the synthesis, and (ii) the claim term N-α-de-protected lacks antecedent basis. Applicants have addressed these rejections by amendment of the claims.

As amended, claim 74, and dependent claims 56, 75-77, 80, and 81, requires as a final step in the synthesis cleaving the target peptide from the pre-sequence peptide. These claims also include the limitation that the coupling efficiency during the synthesis of the target peptide is increased in comparison to the synthesis of the target peptide prepared under the same conditions without the pre-sequence peptide. These limitations

distinguish the methods of the present invention from general SPPS methods known in the art. The claims have also been amended to provide a proper antecedent basis for the claim term N-α-de-protected.

Finally, applicants note that while new claims 82-86 are directed to methods for the synthesis of a peptide conjugate including the target peptide and the pre-sequence peptide, these claims require, among other limitations, that the pre-sequence peptide be homo-oligomeric and that the presence of the pre-sequence peptide increases the coupling efficiency for the preparation of the target peptide in comparison to the synthesis of the target peptide prepared under the same conditions without the pre-sequence peptide.

In view of the amendments to the claims, applicants request that the rejection for indefiniteness be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 56 and 74-81 stand rejected under 35 U.S.C. § 103 for obviousness over U.S. Patent No. 6,113,896 (hereafter 'Lazarus'). Applicants have addressed this rejection by amendment of the claims.

Lazarus describes known SSPS methods, including stepwise addition of amino acids to a chain attached to a solid support.

As noted above, the claims have been amended to more clearly distinguish the method of the invention from general SPPS methods known in the art. Nowhere in

Lazarus is it taught to increase coupling efficiency during the synthesis of a target peptide by including a pre-sequence peptide that is later cleaved, as required by claims 56, 74-77, 80, 81, and 87, or by including a pre-sequence peptide that is homo-oligomeric, as required by claims 82-86.

Support for the Claim Amendments

Claims 56, 74-77, 80, and 81 have been amended. Claim 82-87 have been added. No new matter has been added with these amendments.

Support for the claim term "increases the coupling efficiency during the synthesis of the target peptide in comparison to the synthesis of the target peptide prepared under the same conditions without said pre-sequence peptide," as recited in claims 74 and 82, is found in the specification at page 46, lines 13, to page 48, line 4, and at page 8, lines 6-13.

Support for the synthesis of peptides sequences which are conjugates of formula "X-[target peptide]-[pre-sequence peptide]-Y," as recited in claim 82, is found in the specification at page 16, lines 24-30.

Support for the claim term "pre-sequence peptide consists of from 5 to 7 amino acid residues," as recited in claim 83, is found in the specification at page 15, lines 23-27.

Support for a pre-sequence peptide consisting of polylysine, as recited in claim 84, is found in the specification in the examples at pages 31 to 43.

Support for a pre-sequence peptide consisting of -$(Lys)_6$-, as recited in claim 85 is found in the specification at page 38, lines 4-6.

Support for increasing yield or purity using the methods of the invention in comparison to the synthesis of the target peptide prepared under the same conditions without said pre-sequence peptide, as recited in claims 86 and 87, is found in the specification at page 46, lines 13-25, and at page 8, lines 6-13.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested. Applicant claims small entity status under 37 C.F.R. § 1.27. Enclosed is a Petition to extend the period for replying to the Office action for three (3) months, to and including November 17, 2005, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: November 17, 2005

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Jeffrey J. Ellison, Reg. No. 51,649, for Kristina Bieker-Brady

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045